REMARKS

Claims 23, 24, 26, 27 and 28 are pending in the present application.

The issues outstanding in this application in the Office Action dated May 14, 2004 are as follows:

- Claim Claims 23, 24, 26, 27 and 28 were rejected under 35 U.S.C. § 101, and under 35 U.S.C. § 112, first paragraph.

- Claims 24, 26, 27 and 28 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking adequate written description.

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the remarks contained herein.

I. Rejection under 35 U.S.C. § 101

Claims 23, 24, 26, 27 and 28 are rejected under 35 U.S.C. § 101 as lacking a specific or well established utility. Applicants respectfully traverse.

Under the utility guidelines, the initial burden is on the Patent Office to establish a *prima facie* case of utility, which requires sufficient evidentiary basis. According to the MPEP 2107.02, where the asserted utility is not specific or substantial, a *prima facie* showing contains the following:

1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;

2) Support for factual findings relied upon reaching this conclusion; and

3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

The *prima facie* showing must be set forth in a well-reasoned statement. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions. Applicants assert that the Examiner has failed to meet the requirements of a *prima facie* showing of no specific and substantial credible utility.

An applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101. See, e.g., *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977). The MPEP provides further guidance in the case of claims concerning polynucleotides. "Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention." MPEP 2107.01.

Applicants note that a specific biological activity has been indicated in the present application. See page 6. Applicants also note that this activity was reasonably correlated to a disease condition. See page 13, lines 21-29, in which Applicants note the expression of SEQ ID NO:16 is nearly identical to GDF-9, which when defective in mice, is related to infertility. One with skill in the art would conclude from the specification that a specific and substantial utility is clearly outlined for the claimed invention.

Furthermore, the Examiner states that establishing a utility for the mouse *01-236* gene fails to establish a utility for the human *O10236* gene. Applicants assert that one with skill in the art would conclude that testing the function of a gene in mice would provide a reasonable correlation for the function of that gene in humans. Applicants submit herewith a Supplemental IDS including an NIH report of the history of the mouse as a model system for human disease, and "Animal models of ovarian cancer," Vanderhyden BC, Shaw TJ, Ethier JF. *Reprod Biol Endocrinol.* 2003; 1(1): 67, to demonstrate that one skilled in the art

considers the mouse model to be an acceptable model as a predictor of disease in humans. *In re Brana*, 51 F.3d. 1560 (Fed. Cir. 1995). The Patent Office in this instance appears to be confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval for marketing drugs. *Id.* at 1568.

> We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans.

Id. at 1667 citing *In re Krimmel*, 292 F.2d 948, 952 (CCPA 1961).As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980.

Applicants conclude that the Office has not properly established a *prima facie* case of lack of specific and substantial utility, and respectfully request withdrawal of the 35 U.S.C. 101 rejection.

II. Rejection under 35 U.S.C. § 112

Claims 23, 24, 26, 27 and 28 are rejected under 35 U.S.C. § 112, first paragraph since the claimed invention lacks a specific or well established utility. Applicants respectfully traverse.

Applicants assert that the claimed invention has an asserted utility as discussed above. Thus, in view of the above comments, Applicants request that the rejection be withdrawn.

III. Rejection under 35 U.S.C. § 112

Claims 24, 26, 27 and 28 are rejected under 35 U.S.C. § 112, first as allegedly lacking adequate written description. Applicants respectfully traverse.

Claims 24, 26, 27 and 28 are to functionally defined polynucleotides. The Revised Interim Written Description Guidelines set forth examples of allowable polynucleotide claims defined by functional language, see Example 9, "...a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention." Applicants assert that the stringent hybridization conditions set forth do not encompass an unreasonably large genus, but rather a genus that is strictly defined. Additionally, due to the high degree of homology between mouse and human *Npm2* genes, see Figure 15, it could be predicted that the species disclosed in the specification as binding to the mouse *npm2* gene would also hybridize to the human *Npm2* gene. Thus, according to the Revised Interim Written Description Guidelines, claims 24, 26, 27, and 28 are written in allowable format.

Applicants note that, during examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) Applicants submit herewith in a Supplemental IDS, "Different functional domains of TAFII250 modulate expression of distinct subsets of mammalian genes." O'Brien T, Tjian R *Proc Natl Acad Sci U S A.* 2000 Mar 14; 97(6): 2456-2461, as support that one with skill in the art understands the term "modulate" without further definition.

Applicants respectfully request that the rejection under 35 U.S.C. § 112 be withdrawn.

In view of the above remarks, Applicants believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01925US2 from which the undersigned is authorized to draw.

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Respectfully submitted,

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